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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,187	04/21/2000	Amy E. Baker	425802000200	7012

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1617	18

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/557,187	BAKER, AMY E.	
	Examiner	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7-11,13 and 15-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7-11,13 and 15-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of Amendment filed on March 10, 2003. Claims 1, 2, 4, 5, 7-11, 13, 15-22 are pending. Claim rejections under 35 U.S.C. § 103 as indicated in the previous Office action dated March 10, 2003 are modified to meet the amended limitation.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 4, 5, 7-10, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzjarrell (US 5759559) in view of Briggs et al. (US 5976 521) ("Briggs") and Guang Lin et al. (US 5612324) ("Guang Lin").

Fitzjarrell teaches an acne treatment regime which includes topical spray of an anti-acne solution onto the effected area. See col. 1, lines 49 – 55. While preferably about 2 to 10 percent by weight of niamicine is employed in the topical spray solution in the patent, the prior art also teaches that salicylic acid is used and well-known anti-acne agent used for mild acne. See col. 1, lines 17 – 28; col. 2, lines 28 – 36. The reference teaches that the invention can be applied to difficult areas to treat, such as nose, chin, shoulders, neck, etc. See col. 1, lines 39-42. The recitation "for administration as such only to non-facial body skin" is merely directed to an intended use and not a structural limitation. Thus no patentable weight is given to the preamble.

Fitzjarrell fails to teach to formulate salicylic acid in alcoholic solvent or the pH of the composition.

Briggs teaches an anti-acne composition comprising salicylic acid. See abstract. To deliver salicylic acid in aqueous solution but without the salicylic acid precipitating out of solution, the reference teaches that the salicylic acid is dissolved in aqueous/alcoholic solution. See col. 1, line 63 – col. 2, line 37. From about 0.1 to about 10 % of salicylic acid is used. See col. 2, lines 61 – 67; instant claim 10. Ethyl alcohol is preferred and used in the illustrated formulation for the aqueous phase, which contains salicylic acid and an additional anti-acne agent, azelaic acid. See col. 3, lines 1 – 47; col. 11, lines 35 – 40. See instant claims 7 and 8. Briggs further teaches that the preferred pH of the final aqueous/alcoholic anti-acne active solution is preferably in the range of about 1-7. See col. 3, lines 37 – 47. See instant claims 1, 2, 4, and 5. The recitation "whereby the likelihood of the fine mist spray causing nasal irritation and coughing is reduced" is viewed as an obvious property of the solution having pH of above about 5, which is within the pH range taught by Briggs.

Briggs fails to teach denatured ethyl alcohol.

Guang Lin teaches anti-acne composition comprising salicylic acid in aqueous/ethanol carrier. See Examples. SD (specifically denatured) alcohol is used in the formulation. The reference also teaches that a preferred pH range of the salicylic acid solution is between 2 to 5.5. See col. 4, lines 5-18.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the spray composition of Fitzjarrell by substituting salicylic acid for the anti-acne actives employed in the patent because of the expectation of successfully producing a mild anti-acne spray solution. The skilled

worker would have been further motivated to employ ethanol or denatured ethanol for solvent or carrier of the solution, as suggested by Briggs and Guang Lin, because of the expectation to successfully solubilize salicylic acid in aqueous solution without the salicylic acid precipitating out of the solution.

All components are old and well known in acne medication art. Nothing nonobvious or unexpected is seen in combining the ingredients well known in the art. See MPEP § 716.02.

2. Claims 2, 11, 13-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzjarrell, Briggs, and Guang Lin as applied to claims 1, 4, 5, 7-10, and 21 above, and further in view of Stone (US 4322020) and Sciarra (Remington: Practice of Science and pharmacy, 19th Ed.).

Fitzjarrell, Briggs, and Guan Lin are discussed above. While Fitzjarrell teaches to use "any suitable spraying device", the combined references above fail to disclose the specific feature of the spray dispenser.

Stone teaches an invertible pump sprayer which is said to overcome the disadvantages of conventional aerosols in cosmetics and pharmaceutical applications. See col. 1, line 9 – col. 2, line 65. The reference teaches that pump sprays are preferred over aerosols because of the clogging problem in the aerosol valves and environmental concerns. See col. 1, lines 22-35. In Example 1, the reference describes a topical anesthetic solution spray having an average particle size of approximately 200 microns when the viscosity of the solution is 38 cps. at 20 °C.

While the particle size does not expressly meet the limitation of instant claim 2, the reference teaches "the particle size of the spray will vary with the rheology of the liquid being sprayed as well as with the orifice size." See col. 5, lines 44 – 49. It is further disclosed, "the lower the viscosity of the liquid and the smaller the orifice size, the smaller the particle size obtained." Thus it would have been obvious to a routineer to expect that a lower particle size would have been produced from a less viscous solution.

Stone fails to disclose the volume of spray per actuation.

Sciarra teaches that topical aerosols have been used for preparations for the treatment of acne. See p. 1676, 1st par. He also teaches that for topical sprays particles are produced in size from 50-200 μm, which meets claim 2. See p. 1677, 4th par. It is further disclosed that for a typical metered-dose aerosol delivery system for pharmaceuticals, the size of the chamber can be modified so that about 25-150 μL of the solution can be delivered per actuation, which meets claim 19. See p. 1688, 6th par. – p. 1689, 1st par.

Given the general teaching of using a suitable spray dispensing device for the anti-acne solution in Fitzjarrell, it would have been obvious to a skilled artisan at the time the invention to have further modified the anti-acne spray of the combined references by employing the Stone spray dispenser, as motivated by the teaching therein, because of the expectation of successfully producing an anti-acne spray product that produces fine mist spray without the disadvantages of aerosol, such as clogging or harmful effects to the environment.

It would have been also obvious to the skilled artisan have looked to the prior art such as Sciarra for suitable dosage of the anti-acne medication. It is obvious that the routineer would have found a motivation to modify the pump spray in the combined references by designing the chamber size as taught by Sciarra to adjust the delivered amount per actuation as desired.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 4, 5, 7-11, 13, and 15-22 have been considered but are moot in view of the new ground(s) of rejection in part and not persuasive in part.

Applicants assert that the Fitzjarrell reference fails to teach 'fine mist' pump spray. Examiner takes the position that the general teaching that any suitable spraying device such as conventional pump or aerosol sprayers can be used in Fitzjarrell renders the claimed fine mist pump spray obvious. Also the Stone reference renders it obvious to use a pump spray to produce fine particles of topical compositions.

Applicants argue that the reference fails to teach using salicylic acid, referring to a statement that the prior art treatments are "often unsuccessful and many have significant side effects". Examiner takes the position that the subject "these [prior art] treatments" refer to the severe acne treatments that are disclosed immediately proceeding to that sentence (i.e., "tetracycline, 13-cis-retinoic acid and other prescription drugs). Even if "these treatments" included mild acne medications, the teaching is not specific enough to negate the obviousness that a skilled artisan would have been motivated to substitute salicylic acid for niacinamide in order to produce a

mild acne spray composition. It is well settled in patent law that that a known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use. See In re Gurley, 27 F.3d 551, 554, 31 U.S.P.Q. 2d 1130, 1132 (Feb. Cir. 1994). In this case, even if the Fitzjarrell patent described salicylic acid as an inferior substitute for niacinamide, the fact that salicylic acid is a conventional medication for mild acnes does not change and would render the claimed invention obvious. Examiner maintains the position that substituting salicylic acid for niacinamide would have been obvious either in view of the Fitzjarrell reference alone or in combination with Briggs and Guang Lin references.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
May 20, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER
6/1/03